

Emerging Issues in HIV/AIDS Health Services Research:

Defining a Research Agenda for California

September 2002

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Universitywide AIDS Research Program
<http://www.ucop.edu/srphome/uarp>

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EMERGING ISSUES IN HIV/AIDS HEALTH SERVICES RESEARCH:

DEFINING A RESEARCH AGENDA FOR CALIFORNIA

DEVELOPED BY
**THE CALIFORNIA CONSORTIUM ON
HIV/AIDS HEALTH SERVICES RESEARCH**

IN COLLABORATION WITH THE
**CALIFORNIA DEPARTMENT OF HEALTH SERVICES, OFFICE OF AIDS
AND THE UNIVERSITY OF CALIFORNIA, UNIVERSITYWIDE AIDS
RESEARCH PROGRAM**

SEPTEMBER 2002

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ACKNOWLEDGEMENTS

This document is a product of an ongoing collaboration between the California State Office of AIDS (OA) and the University of California's Universitywide AIDS Research Program (UARP). From their inception in 1998, these collaborative efforts focus on strategic planning for health services research with the ultimate aim of informing statewide policy and program development. Serving as key advisors to the process, OA- and UARP-funded health services investigators came together in 2000 and 2001 to form the California Consortium on HIV/AIDS Health Services Research (the Care Consortium). This research agenda has been generated in large part through the efforts of the Care Consortium.

UARP and OA would like to thank the investigators composing the Care Consortium who put much time, effort and expertise into the development of the research strategies contained in this report.

Funding for the ongoing work of the Care Consortium and for the production and distribution of this document has been provided by the OA.

For additional copies of this report, please contact UARP at 510/987-9855 or uarp@ucop.edu.

INTRODUCTION

Health services and policy research can contribute to improvements in the health care delivery systems that affect health outcomes among individuals infected with HIV. Just as services can be improved when informed by studies of efficacy, equity, and effectiveness, research itself is most effective when it is conditioned by constant reexamination of what new knowledge is needed. This iterative process may be even more necessary with regard to research on HIV services because of the resource-intensive, constantly changing nature of treatment and because individuals affected by the virus often face complex health challenges. The delivery of quality, consistent care is conditioned by multiple factors, some of which are understood and many of which remain unexplored.

In light of the current state of publicly-funded care delivery, this document recommends needed research with the potential to improve the delivery of health care to HIV infected individuals and inform the policy development that underlies it; this research agenda contains guidance for investigators and funders seeking to address and support research exploring new and critical questions facing California's HIV/AIDS health services systems.

DEVELOPMENT OF THE RESEARCH AGENDA

This document is a result of work begun by the University of California's Universitywide AIDS Research Program (UARP) and the State Office of AIDS' (OA) collaboration on health services research planning. Since 1998, the collaboration has sponsored efforts such as the formation of the Care and Treatment Research Advisory Committee (CTRAC) and the 1999 conference on HIV/AIDS Care and Treatment Research in California. The aim of these efforts has been to provide forums for developing recommendations for future research initiatives addressing HIV/AIDS health services delivery in California.

Prior to the development of this document, OA and UARP planning efforts successfully produced a broad set of recommendations for health services researchers (see Appendix D). This research agenda represents the next step, which has been to use these recommendations as a foundation for developing an array of specific, targeted priority questions to strategically focus future research efforts. To accomplish this goal, the California Consortium on HIV/AIDS Health Services Research (The Care Consortium) was formed in 2000. Comprising OA- and UARP-funded health services and policy research investigators from across California, the Care Consortium was charged with developing a set of specific questions to guide statewide health services research planning and support in the coming

years. Specifically, the Care Consortium was charged with the following aims:

- ❑ To identify gaps in knowledge regarding access to and delivery of effective, efficient, and equitable HIV/AIDS health services.
- ❑ To develop a set of priority research questions to be addressed in the short and longer terms.
- ❑ To suggest potentially fruitful research strategies to effectively answer these questions.
- ❑ To provide advice to the OA and UARP on research planning and funding.

To accomplish these aims, the Care Consortium met initially to brainstorm ideas for needed research, while keeping in mind the broad recommendations set forth in previous research planning activities. The result of this session was a long list of potential areas for research focus (Appendix A). Subsequent to this initial idea-generating period, Consortium members ranked the questions, prioritizing those most needed to improve current care delivery. This document outlines those research areas the Consortium chose as priorities.

After the questions and strategies were developed, a draft of this document was circulated for comment to other identified experts, including members of CTRAC; those in attendance at the September 1999 Care Conference; and members of the statewide planning body, the California HIV Planning Group. Together, these key inputs have provided the foundation for the final document: a current research agenda informed by experts in the field that statewide investigators and funders may use as a guide to future research planning and funding. *The purpose of this agenda is to broaden and strengthen the content of research targeting publicly funded HIV/AIDS health service delivery in California.*

ORGANIZATION OF THIS AGENDA

The next section outlines a set of targeted research questions that emerged as priorities for immediate attention by researchers and funders. These sections also propose strategies for addressing the research questions. The document is organized into sections by research area: Case Management; Payer Source and Continuity of Care; Patients and Providers Communicating About Adherence; Long-Term Health Outcomes Among Individuals with HIV; Provider-Level Influences on Patient Access to Care; and Building Data Infrastructure to Support Health Services Research. The concluding section summarizes the broad outlook for HIV/AIDS health services

research in California with particular attention to what will be needed in the next five years.

SCIENTIFIC ISSUE

CASE MANAGEMENT

Studies have shown that HIV-infected individuals receiving case management services have fewer unmet needs, benefit from better links to primary care, and are more likely to receive HIV medications. However, researchers in the field of health services research face significant challenges regarding measurement across the array of services that define case management. While preliminary findings indicate that case management has the potential to improve access to primary care and ancillary services, few studies have demonstrated the mechanisms or specifics of how these improvements take place. The state of the field currently suggests that research should focus *simultaneously* on developing an operational definition of case management and on addressing the measurement issues surrounding it. Subsequently, rigorous studies that are able to demonstrate the effects of case management on health and service outcomes could be undertaken.

PRIORITIES FOR RESEARCH:

With these issues in mind, a descriptive epidemiologic survey of case management in California is needed. There are three levels upon which to focus an epidemiologic approach to case management: the provider level; the client level; and the organizational level. Research questions should target the following:

- ❑ Define case management, in its various forms, using both qualitative and quantitative criteria.
- ❑ Define expected outcomes and measure actual outcomes. Be mindful of the fact that outcomes exist on multiple levels. For example, expected outcomes may be different for case management that focuses on financial needs versus case management that focuses on treatment adherence. Outcomes can also pertain to the effectiveness of referrals to forms of care or treatment that affect the client's health and well-being.
- ❑ Define and measure quality criteria for case management (i.e., how well are client needs being met by various models/forms of case management).
- ❑ In subsequent phases, examine issues of organizational structure. How does the type of organization, the structure of the delivery system, or the environment in which the organization lies predict outcomes and how does it affect what population is served?
- ❑ Examine cost effectiveness of case management. Are there models of case management or care coordination that are more effective than others?

RESEARCH DESIGN RECOMMENDATIONS:

Research examining a variety of case management or care coordination models can yield both description and cost effectiveness information. As a first step, participant observation would be a useful technique to describe the core services constituting case management and the services peripherally related to it. A methodology needs to be developed to measure the frequency with which case management related “events” occur, both case manager activities and outcomes that might result from those activities. Researchers may want to consider developing a typology of case management to describe the different types, including: social service delivery, medical case management, financial issues, or some other core service or services. This typology could be measured and “doses” of each compared over time.

A sampling strategy for both clients and providers needs to be developed to take a cross-sectional survey of case management in a representative range of environments. Surveys or focus groups could be conducted to determine provider characteristics, services provided, and venue of service provision. As an innovative approach, clients themselves may be a good source of information and help in developing a definition of case management that is grounded in their own experiences. Asking patients about their perception of what constitutes case management, about the client’s identification of a “case manager,” and about the benefits or results of case management could better define the core services and mechanisms by which they effect continuity. This approach begins to address the interaction effects of client and service variables.

An “ethnography” of case management could be a useful component of a descriptive study. Focus groups targeting clients and case managers may help develop epidemiologic definitions for both case management and its constituent activities and the potential outcomes that result from case management. The rapid ethnography techniques being employed by the social anthropologist Susan Scrimshaw should be explored.

Taking a prospective, observational approach to this topic would be an important, but difficult, next step to implement. Panel studies using a population-based sample of case managers in California should be considered. Another approach might be to study prospectively a cohort of HIV-infected individuals, comparing those who receive case management and those who do not.

A randomized trial of alternative forms of case management would constitute the most rigorous study. Before going to clinical trial, it would be important to define the universe of agencies and clients involved with case management and to determine who was performing case management related activities and who was receiving such services. While some case management

guidelines exist (for example, those developed jointly by the San Francisco Department of Public Health and the San Francisco Ryan White CARE Council), many people practicing in the field may not know of them or do not apply them in any consistent manner. Nevertheless, rigorous evaluation of such guidelines may be in order. In this way, the independent effects of the various components could be determined, as could the consistency across definition and service delivery.

Several caveats are warranted with regard to new studies of case management. Consideration should be given to the amount and type of resources available to support case management activities. Resource availability may have clear influence on the number and types of services delivered as well as on the outcomes of service delivery. Researchers should also consider the potential effect that their interventions might have on the results of a study. It may be that during studies of case management, where definitions are developed and tested, an “enhanced” version of the services might be delivered, even when unintended. A prospective observational study may solve this dilemma because it would not involve an intervention. Finally, researchers should not lose sight of the fact that case management is ultimately a client-centered activity, and the consideration of benefits to clients should be incorporated into all research.

PAYER SOURCE AND CONTINUITY OF CARE

Little is known about the effects of changes in health care coverage on the delivery of care and treatment to people with HIV disease. In a few studies health care providers and clients have recounted the disruptions in receipt of consistent quality health care that transitions in health care coverage can cause. Transitions in coverage are often complicated by the fact that both private and public payers are involved. While several well-designed studies have addressed the cost of HIV care, few have addressed systematically the issue of changes or transitions in coverage and their effect on continuity of care, service delivery, patient satisfaction, and health outcomes over time.

Studies are needed to determine whether transitions from one source of health coverage to another affect the initiation or continuation of antiviral therapy. Additionally, payer source or source of insurance coverage needs to be understood separately from cost of care. The relationship between changes in income, job status, and health insurance status has yet to be adequately explored. In particular, what precipitates these changes (i.e., disease progression, an AIDS diagnosis, start of Highly Active Antiretroviral Therapy (HAART)), and how do these changes affect care and treatment?

The largest share of health care costs for people with HIV/AIDS is borne by public programs. California investigators have noted differences in the characteristics of HIV-infected individuals who have different types of insurance coverage. For example, relative to other groups, African Americans tend to be over-represented in Medi-Cal programs while Latinos utilize Ryan White CARE Act-funded providers more often. Furthermore, studies have shown that type of insurance coverage affects the receipt of health care services and pharmaceutical treatment for people with HIV/AIDS. These differences suggest that payer source has significant influence on receipt of care services and that further study with a systematic, statewide approach is warranted.

PRIORITIES FOR RESEARCH:

The search to understand the role of payer source and health insurance coverage for people living with HIV in California suggests the following priorities:

- Undertaking qualitative studies to understand the life histories of individuals with HIV with regard to health insurance coverage and use of services. Such studies would help to outline the life events that predict transitions in insurance status, such as progression to a health status considered legally disabled. An additional line of inquiry would be to explore how changes in source of health insurance are associated with

employment status and income, both of which influence care service access. Employment transitions occur both as people become disabled and as they return to work with improved health status as a result of advances in pharmaceutical therapy. Life transitions of all kinds can undermine continuity of care, especially when different payers lack consideration and anticipation of transition.

- ❑ Investigating the relationship between indicators of disease stage and insurance or payer source in order to fully understand how health care is funded and how funding influences the quality of care. For example, studies should consider whether changes in health insurance coverage affect the initiation and sustainability of treatment and the outcomes associated with it (such as CD4 count, viral load, adverse health events, and hospitalization).
- ❑ Undertaking cost-benefit and cost-effectiveness studies. The results of these studies could enable the delivery of better care to more people by establishing stable forms of health insurance coverage. Such studies could demonstrate the possible benefits of expanding coverage to avert negative health outcomes and the costs associated with them.
- ❑ Exploring the extent to which people with HIV are uninsured would require understanding the mechanisms in place to bring uninsured individuals into programs. In this way, opportunities might be expanded to increase the insurance rate among HIV-infected.
- ❑ Investigating the influence of immigration status on eligibility for health insurance coverage of most kinds.
- ❑ Addressing the issue of uncompensated care because it has major ramifications for the health care system in California. Unknown is the size and scope of the burden facing counties for the uncompensated care of people living with HIV.

RESEARCH DESIGN RECOMMENDATIONS:

Understanding how insurance status and payer source influence service delivery and health outcomes is important, and requires data that are not currently available. In the current system, medical records are often linked to billing systems but not to an individual patient, and little continuity exists across data sources. Cohort and longitudinal studies that are most appropriate to answering the research questions at hand will require databases that are linked to service delivery or a practice site and to an individual patient rather than to the requirements of the payer. This is of particular concern in the case of uncompensated care, which is primarily delivered and accounted for by county health care systems.

Consideration should be given to variation in care delivery when care is funded by different payer sources, because it may reflect an influence of payer source on practice patterns. Reimbursement rates may condition a

provider's treatment choices, as has been evident in general studies of health care delivery. Other variations may exist in the services covered, depending upon the payer. The eligibility criteria defined by different payers may confound the relationship between payer source and health outcomes. For example, individuals with HIV can be excluded from private health insurance coverage because of their serostatus or because the onset of HIV-related disability is often associated with entry into the public care system. As a result, the therapies available to these individuals are a result of the payer source's willingness to cover their care.

Transitions in payer source provide clear rationale for developing collaborations between private insurers and researchers. Linking private data sources to public sources is needed to understand these transitions. Insight from investigators in both private and public settings is needed to account for the complexities created by the multiple health care payer sources. This is particularly true with regard to understanding care continuity and transitions over the course of disease progression and across clinical settings.

SCIENTIFIC ISSUE

PATIENTS AND PROVIDERS COMMUNICATING ABOUT ADHERENCE¹

Most of the literature on patient adherence to HIV antiviral therapy addresses the question, “*Why aren’t patients taking their medications?*” and involves elaborate methods of assessing adherence. These analyses are broken into patient variables (e.g., mental status, health beliefs), social variables (e.g., lack of support, dysfunctional relationships), illness variables (e.g., lack of symptoms), treatment variables (e.g., expense, side effects of medications), and patient/provider relationship variables (e.g., lack of trust, poor rapport). However, a different approach to these important issues may be to ask, “*Why aren’t patients telling us they are not taking their medications?*” This question is important because very little research has addressed questions about why patients do not discuss non-adherence with their providers.

PRIORITIES FOR RESEARCH:

In addressing issues of provider-patient communication about adherence issues, there are several levels at which research questions can be posed. Providers often assume that they are able to provide an open, non-judgmental, and enlightened atmosphere in which to communicate intimate concerns, but there may be many factors involved in a provider-patient encounter that hinder open communication about non-adherence. Examples follow of influences from each level that need to be examined.

□ Belief Systems:

Aspects of patient belief systems influence communication in clinical settings. Beliefs can condition communication singly or in combination with the dynamics created by the patient-provider relationship.

- *Simpatía* - In Latino culture, a premium is placed on harmonious relationships and it would be disrespectful to tell the physician, an authority figure, that the advice given is not being followed.
- Perceived “toxicity” from the medications and the need to “cleanse” the body might alter how a patient takes medications.

¹ Patient-provider communication is just one aspect influencing adherence and treatment decisions. The Care Consortium agreed that the field of adherence research is broad and all facets of adherence deserve attention. Consortium members decided to focus on communication in clinical settings because they perceived it to be a priority area that has been understudied.

- Patients may believe that the medical establishment and pharmaceutical companies are not truly interested in the patients' well-being. This distrust may be more prevalent in communities of color and in impoverished communities.
- A patient's social networks very often influence behavior. Informal consultation among members of a social network can influence adherence and other health behaviors. Researchers should identify these relationships and their influence so that providers can consider them when delivering care.

□ **Provider-Level Assumptions:**

In general, medical education does not include significant training on effective communication techniques. This presents a challenge to medical educators and policy makers to encourage change in the way that providers are trained. Some issues that deserve further investigation, and upon which this education should potentially focus include:

- Provider body language can inadvertently shut down conversation in a provider-patient encounter.
- Providers may unconsciously indicate that they are looking for a certain type of answer to questions regarding adherence. Consider the different answers that might be elicited by asking: "So, you are taking all your medications, right?" versus "Many patients report difficulty taking all their medications; in your case would you say you miss one, two, or more doses per week?"
- Provider biases based in class or cultural differences may make patients uncomfortable sharing about their health.
- Another level of communication occurs between providers caring for the same client. If providers do not routinely communicate with each other and share clinical notes and perceptions, a patient's care may not be maximized.

□ **Institutional-Level Resource Constraints:**

- Medical practice is often subject to organizational and system-level influences that can affect communication between providers and patients. A physician's ability to elicit information on adherence may be a function of the amount of time allotted to each patient. The impact of organizational policy and procedure on provider-patient communication needs to be examined.
- The complexity of care delivery in different clinical sites may prove to be a barrier to access and quality of care. For example, how does receipt of care in several sites influence communication between providers and how does this influence patient adherence?

RESEARCH DESIGN RECOMMENDATIONS:

In general, issues of patient-provider communication and trust require a multidisciplinary approach to research that incorporates methods from myriad disciplines. Medical anthropology, sociology and psychology can provide some methods and theories promising for this kind of research. Health services researchers have not often utilized these approaches, and would benefit from the approaches used by those who have successfully explored these issues. Furthermore, a systematic examination of interdisciplinary methodology could lead to the development of an approach to be used for multiple studies of communication in health care settings.

BACKGROUND INFORMATION:

While few sources are available that speak to these issues, some initial sources to consult include:

- “Research Designs in Medical Anthropology,” (Chapter 15) in Anthropological Research: The Structure of Inquiry, by Pertti and Gretel Peltó, 1996 (Praeger).
- “Barriers and Facilitators of HIV-Positive Patients’ Adherence to Antiretroviral Treatment Regimens” by Kathleen Johnston Roberts in *AIDS Patient Care and Studs*, volume 14, number 3. Roberts attempts to describe from the HIV-positive patients’ perspective barriers in adhering to antiretrovirals and strategies to maximize adherence. The methodology involved in-depth face-to-face interviews with 28 patients. The interviews were transcribed and multiple readings were performed to identify major ideas or themes. A computer-based text search and retrieval program was used to help manage the data during the coding process. Another strategy included frequently confirming that the interviewees understood what was being asked. The method of analysis and results were critiqued by two independent medical sociologists.
- Latino Gay Men and HIV: Culture, Sexuality, and Risk Behavior, by Rafael Díaz (1997: Routledge). This work is probably the most comprehensive regarding the barriers to protection within the Latino gay male community.
- “Latinos and HIV: Cultural Issues in AIDS” (Chapter 8; pp 917-924), by Barbara Marín and Gomez, C. (1999). In: Cohen PT, Sande MA, Volberding PA, eds. The AIDS Knowledge Base. Third Edition. Lippincott Williams & Wilkins, Philadelphia.
- Researchers interested in exploring patient-provider communication should look beyond HIV for frameworks and evidence. Research in the areas of primary and family medical care provision have extensively examined the topic of patient-provider communication.

SCIENTIFIC ISSUE

LONG TERM HEALTH OUTCOMES AMONG HIV-INFECTED INDIVIDUALS

The recently released National Institutes of Health *Fiscal Year 2002 Plan for HIV-Related Research* contains the following recommendation regarding one scientific area deserving of emphasis:

Determine the biological characteristics, sociocultural factors, and health services issues that alter the dynamics of transmission and disease progression in men and women, as well as in the various racial and ethnic groups.²

This recommendation has particular urgency as we understand more about the course of disease progression as affected by long-term use of antiviral therapy. The long-term health outcomes of HIV disease in interaction with the physiological effects of HAART are not well known, but their initial manifestations have clear implications for clinical practice, health services use, and research. With these issues in mind, research studies should address differences in long-term outcomes by age, gender, ethnicity, risk group, setting of care, type of provider, and class of medication prescribed. These questions are particularly important to ask in California, where HIV's impact has been quite different in terms of the epidemiologic profile compared with the rest of the country.

Many different research methods may be necessary to understand the role that sociodemographic factors play. Multiple methods may be used in study design including ecological studies (repeated cross-sections from specific populations), cohort studies (which may utilize either existing or prospective data sources), case-control studies, and innovative adjunctive studies that may require some additional data collection. Endpoints addressed in research should be both proximal outcomes (such as HIV RNA levels, CD4+ cell counts, and quality of life) and longer term outcomes (such as survival and progression of disease).

PRIORITIES FOR RESEARCH:

Important research questions include:

- ❑ What are the predictors of morbidity and mortality in the antiretroviral era?
- ❑ What is the affect of antiretroviral prescription patterns on clinical outcomes?

² National Institutes of Health, Office of AIDS Research. *Fiscal Year 2002 Plan for HIV-Related Research*, p.3. <http://www.nih.gov/od/oar/public/pubs/FY2002Plan.pdf>.

- ❑ What is the affect of co-infection with the Hepatitis B Virus (HBV) and/or the Hepatitis C Virus (HCV)?
- ❑ What are the clinical correlates of sustained virologic suppression?
- ❑ What are the long-term implications of structured treatment interruptions?
- ❑ What are the prevalence and incidence rates for rare clinical complications (i.e., myocardial infarction (MI), stroke and diabetes)?

RESEARCH DESIGN RECOMMENDATIONS:

The following detailed subject areas provide examples of outcomes research approaches that utilize several different frameworks or platforms. By considering several research platforms, investigators can address multiple long-term outcomes research questions using one core data set and provide an efficient means for conducting outcomes research. These research platforms can consist of existing data sources, existing prospective cohorts, innovative adjunctive studies, and optimally, the pooling of more than one of the above data sources. Ideally, platforms would include not only information from clinic settings but also broader population-based data sources. It will also be necessary to include data sources that target specific populations (e.g., women, drug users, and the homeless) in order to address rare outcomes or those specific to these populations.

❑ Platform: AIDS Drug Assistance Program (ADAP) database

Broad questions to be explored regarding prescription patterns and their influence on survival include:

- What are the antiretroviral prescription patterns of clinicians in California?
- How have prescription patterns changed since the advent of protease inhibitors?
- How do prescription patterns differ by setting of care, type of provider, age, gender, ethnicity, and Centers for Disease Control (CDC) risk group?
- Which of the above covariates predicts the “early adoption” of new medications?

These questions may address more formative research using retrospective methods and existing data in the ADAP databases. The ADAP database may be used in conjunction with the Medi-Cal database to explore both prescription and service delivery patterns. When the ADAP database is linked with this and other data sources, such as death registries, additional core outcomes-centered research questions can be addressed. These include:

- How do the prescription patterns of survivors differ from those who have died since the advent of protease inhibitors?
- What is the best “first line” therapy?
- What is the best “second line” therapy?
- What is the relationship of medication class (protease inhibitors vs. non-nucleoside reverse transcriptase inhibitors) to survival?
- What is the relationship of “early adoption” of new medications to survival?

Variables could include demographic characteristics, start and stop dates of antiretroviral medications, and date and cause of death. Variables could be created to identify each individual’s first, second, and salvage regimens, the dates associated with these regimens, and each class of antiretroviral medications. Finally, individuals and clinicians could be classified as early adopters based on length of time from approval of medications to prescription for each individual.

These research questions can be addressed using retrospective case-control methods. Investigators may choose to control for or match on important covariates. Clinicians could be asked to provide reports on the next “n” patients that the provider identified as appropriate for a treatment change. Reason for treatment change and decision tree analysis could be applied in order to identify what factors clinicians take into consideration. These factors would then be correlated to predictors of treatment outcome to assess whether current treatment patterns match estimates of “best practice.”

□ **Platform: Sentinel Database**

Assembly and maintenance of a sentinel database would provide a long-standing platform upon which current and future discrete data analysis plans could be based. The database would have both retrospective and prospective components. A multitude of research questions could be addressed including the broad question, “What are the predictors of mortality?” Specific research questions could include:

- What are the prevalence and incidence of rare clinical complications (i.e., MI infarction, stroke and diabetes)?
- How do interruptions in HAART affect:
 - survival?
 - immunologic response to therapy?
 - virologic response to therapy?

- time to virologic failure?
- What are the clinical correlates of sustained virologic suppression?

Each component database would contribute a core set of variables based on agreement among databases and investigators. These core variables might include:

- Date of infection/first HIV+ test
- Date of first antiretroviral (ARV) treatment
- History of ARV treatment
- History of opportunistic infections and malignancies
- New opportunistic infection and malignancies
- Other key conditions (e.g., MI, stroke, diabetes, osteoporosis and lipodystrophy)
- Nadir CD4+ cell count
- Peak HIV RNA level
- CD4 and viral load since initiation of HAART (date and value)
- Other laboratory results (e.g., cholesterol, triglycerides, and fasting glucose)
- Record of start and stop of ARV treatment since initiation of HAART (medication and date of start and stop)
- Date and cause of death

Existing data sets include the California Death Registry, HIV Watch (San Francisco General Hospital electronic medical record), Kaiser Permanente, the UCSF Community Consortium Observational Database, and the CHORUS database (funded by Glaxo Wellcome).

❑ **Platform: HCV Database**

Little is known about the interaction of HIV and HCV. Formative research questions yet to be addressed include:

- How does HCV affect the overall disease course of HIV?
- What is the prevalence of HCV among HIV-infected individuals?
- What proportion of HIV/HCV-positive individuals are appropriate to receive treatment for HCV?

- Among those who are appropriate for treatment, what proportion are receiving treatment?
- Does receipt of appropriate treatment differ by age, gender, CDC risk group, setting of care, or type of provider?

Outcomes-focused research questions yet to be addressed include:

- How does the survival of HCV-positive individuals differ from that of others with HIV, with and without HCV treatment?
- Does HCV affect the efficacy of HAART as measured by:
 - survival?
 - immunologic response to therapy?
 - virologic response to therapy?
 - time to virologic failure?
- What proportion of individuals with HCV utilize treatment?
- How do active injecting drug users differ from others with HIV and HCV in liver function, access to treatment, effectiveness of treatment, and overall prognosis?

One way to address these and additional research questions is to utilize data from broader, population-based research studies. As an example, serial cross-sectional research designs among active injecting drug users could be combined with existing data to create sentinel measures. In such a context, behavioral and biomarker survey information can be collected. By linking this information with existing data, investigators can assess the rate of utilization of care and create a prospective case-control study to compare active injecting drug users to others with HCV. HIV-related variables for this data set might be similar to those in the sentinel database. Additionally, information on hepatic variables would be important, including liver function test results, HCV viral load, and liver biopsy staging results (date and value for each variable).

Data for a core HCV database should consist of a prospective observational cohort. Investigators may choose to merge these data into one cohort or to leave them as serial cross-sections in order to more quickly address a subsection of the above research questions.

PROVIDER-LEVEL INFLUENCES ON PATIENT ACCESS TO CARE

Characteristics of the health care setting, including provider-level and organizational-level factors, can have a profound influence on patient care. Provider caseload volume has been associated with health outcomes among patients in hospital inpatient settings treated for HIV-related and other conditions, such as acute MI. Higher volume hospitals may achieve better outcomes because of provider- and organizational-level factors associated with service delivery. The larger the caseload, the greater the practice expertise of the providers delivering care and the greater the delivery setting to accommodate these levels. For example, high-volume hospitals may have, among other characteristics, greater proportions of board-certified physicians and better ratios of registered-nurse-hours to patient. While the relationship of HIV/AIDS patient volume to outcomes has been examined in studies of inpatient care, it has not been addressed in studies of outpatient treatment services.

PRIORITIES FOR RESEARCH:

Research has demonstrated that strong predictors of patient access to quality health care include having health insurance, a higher income, a regular primary care provider, and other sources of ongoing health care. These indicators may predict the prevention of some health problems and the adequate treatment of others, but they do not apply as consistently, or in the same ways, in the case of HIV/AIDS. For example, patient characteristics such as higher income may not predict patients' access to quality health care in the same way as they might, for example, in the treatment of congestive heart failure or other serious conditions. For individuals with HIV, access to quality health care may be more a function of system-level factors, such as caseload volume and the expertise and availability of health care professionals.

Barriers to quality health care can be divided into three major categories: financial, structural, and individual. Structural barriers are a key factor in the delivery of care to HIV-infected individuals. A key structural barrier is the inadequate number of health care providers or specialists equipped to deliver care. Such deficiency is influenced not only by the availability of qualified providers, but also by the number of patients each provider sees and the degree of exposure that patients have to those regarded as experts. These factors suggest the following questions:

- ❑ Do health outcomes related to HIV outpatient care and treatment differ as a function of patient volume in a care setting?

- ❑ In regard to following recommended treatment guidelines, how are provider behaviors in outpatient, low-volume practices different from provider behaviors in outpatient, high-volume practices? And how are these differences associated with health outcomes and morbidity of patients receiving care?
- ❑ To what extent is the care in low- or high-volume practices falling below, meeting, or exceeding standards of practice?
- ❑ What are the primary areas of deficit in low- and high-volume practices, individually and combined?
- ❑ How do organizational-level factors influence the availability of experienced providers?
- ❑ Are organizational-level factors associated with patient-level outcomes such as morbidity and mortality?

RESEARCH DESIGN RECOMMENDATIONS:

In order to address this critical issue, a cross-sectional study utilizing a multi-staged approach is needed. Such a study should be stratified by high- and low-volume caseload and delivery site type and size. Such a study can be conceived in “stages” as follows:

❑ Stage One:

Objective: Identify the number and general characteristics of the wide range of health providers and clinics delivering aspects of primary care, case management, and treatment to clients with HIV/AIDS in the state.

Method: Evaluate the quality and timeliness of data available through ADAP data sets and pharmaceutical company listings. Determine whether practices can be differentiated along two dimensions: number of patients in caseload and number of patients on combination medication regimens. Examine the distribution by region and corresponding statistics of reported number of AIDS cases per region using OA data.

Research Questions:

- What is the ratio of providers to patients by region and by AIDS case distribution?
- What are the characteristics of these providers by region - specifically, what is the caseload volume and what are the practice trends (monotherapy or combination therapy, with and without protease inhibitors)?

□ Stage Two:

Objective: Identify the characteristics, HIV education, and training of health care providers (primarily doctors and nurses) delivering HIV treatment in high- and low-volume practices in selected areas of the state.

Method: Conduct a short telephone interview with a stratified random sample of providers in low- and high-volume practices to determine provider and caseload characteristics, practice policies surrounding introduction of combination therapy, and extent of monitoring for treatment adherence.

Research Questions:

- Does the HIV education and training experiences of providers differ by region and as a function of patient volume? If so, in what respects?
- Do these practices include specific adherence initiatives or programs? If so, what kind (adherence chart reviews, chart flagging, telephone tracking systems, patient self-monitoring, etc.)?

□ Stage Three:

Objective: Determine the specific practices that providers use to educate clients about HIV and HIV treatment. Determine how providers monitor client adherence behaviors.

Method: Sample patient outcome data in selected low- and high-volume practices. Identify policies and procedures specific to low- and high-volume practices regarding patient nonadherence and loss to follow up. Sample patient outcome data in select low- and high-volume practices with respect to health status, HIV morbidity, and treatment adherence.

BUILDING DATA INFRASTRUCTURE TO SUPPORT HEALTH SERVICES RESEARCH

The scientific issues discussed in this agenda share a key commonality: understanding them requires the assembly of complete and accurate data upon which rigorous analyses can be based. While this is true for all research questions, the newly emerging topics suggested in this document also require innovative ways to access, link, and use data. The necessity for information and infrastructure adequate to support data access was a constant theme in the meetings that led to the development of this research agenda. Several different approaches to supporting data development emerged and are outlined below.

LINKING DATA SETS

While there is a need to support accessibility of data of all kinds, there are several databases in existence that could be linked to provide more complete access to patient-level data for HIV health services research. This is usually accomplished with a patient identifier; establishing database linkages may be expedited if they occur within a regulatory agency, such as the OA. Once the data are linked, the combined data set could be updated regularly and made available to investigators. Some suggested linkages with the potential to answer important HIV health services questions are as follows:

- ❑ Link ADAP and Medi-Cal data and generate regular reports on utilization and expenditures.
- ❑ Create sentinel databases that track HIV incidence, prevalence, use of care services, and outcomes over time (see *Long-Term Outcomes* above).
- ❑ Link state and federal databases (for example, link Medicaid to Medicare, the Medical Expenditure Panel Survey, or the Supplemental HIV/AIDS Survey).
- ❑ Link HIV-specific and vital statistics registries.
- ❑ Establish relationships and data sharing collaborations with private payers so that public and private health care data can be used concomitantly.

DATA QUALITY IMPROVEMENT

Data are only useful and meaningful when they are collected with attention to their quality. For this reason, and because complete and accurate reporting of health care data is often difficult to ensure, the need for ways to

improve data quality was emphasized by the investigators contributing to this research agenda. The key to improving quality and accessibility of data is establishing infrastructure to support data collection and use at the state level. While researchers suggested that international examples might be instructive, there was a general call for increased attention to infrastructure by the state agencies responsible for data collection and storage. In particular, the following strategies were suggested:

- ❑ Develop ways to encourage and provide incentives for the collection of quality data in provider settings.
- ❑ Broadly disseminate data access policies.
- ❑ Establish a regularly maintained website with information on data collection and use of data.
- ❑ Hire or appoint a liaison at the state level for investigators interested in accessing state and other data sources.
- ❑ Establish a working group to address the feasibility of accessing and building links between private and public insurance provider data sources.

DATA USERS GROUP

Incumbent upon the users of data is the development of a group or resource that will encourage collaboration and information sharing regarding data sources and data use. Such a group might meet in person or establish a website for exchange of sources, ideas, and calls for research. The website would serve as a central place to suggest and refine research questions and the use of data to answer them.

CONCLUSION

OVERALL THEMES

The questions and strategies for research posed in this document reflect a call to understand the interaction of multiple factors influencing health and health care delivery. Investigators have suggested that questions be approached from multiple levels: individual, organizational, and structural. This complexity of influences must be considered in light of the uniqueness of the California health care landscape. The structure of the health care system, the diversity of the general population and those affected by HIV, and the unique characteristics of provider and clinical settings create a challenging environment in which to undertake research. These factors are contextualized by a changing clinical landscape where progress in treatment and prevention has changed and continues to change.

Across the research areas prioritized by participating investigators, there was great variation in the state of a given field. For example, in the areas of case management and provider communication, formative or definitional research was suggested. Questions targeting long-term outcomes and access benefit from nuanced analyses of large data sets. Payer source questions may benefit from both key informant interviews and use of data from state and federal sources. Regardless of the development within each research area, the broad recommendation to those undertaking and funding new research is to innovate in approach and method. Investigator recommendations suggest borrowing the best approaches from other disciplines, especially application of new methods to the questions at hand.

USING RESEARCH RESULTS

This document reflects more than research guidance; it also demonstrates the utility of collaboration across academic-, government- and community-based partnerships. When multiple stakeholders come together, the variety of uses for research become apparent.

This fact should be emphasized with regard to policy forums. Investigators and users of research results have not often effectively conveyed the value of these results in policy settings. It is incumbent upon researchers and funders to seek out ways to disseminate research findings in ways that can serve policy and program development.

To effectively serve policy and program aims, innovative approaches to dissemination are in order, just as they are in the development of new approaches to research. Fortunately, the need for dissemination occurs at a time when there is increasing emphasis among public funders on research, evaluation, and monitoring. Federal funders are facing increasing calls for

fiscal accountability in HIV and other health services areas. If investigators and funders can work together to develop approaches to research that serve program, policy, and system development, the end-users of research, including policy makers and program planners, can also benefit.

Collaboration, dissemination, and application of research results are crucial to developing resources for continuing research. Clearly, the research designs proposed in this document require significant resources for implementation. In an era of budget shortfalls at local, state, and federal levels, it is incumbent upon health services researchers to make a stronger case for the expenditure of scarce resources on research and evaluation activities. Streamlined research activities developed in collaboration with local providers may be more attractive to funders. Evaluation protocols that include analyses of program efficiency may be more attractive. In the long term, the promise that research holds to serve program effectiveness and efficiency will justify the investment.

APPENDIX A: COMPREHENSIVE LIST OF HEALTH SERVICES AND POLICY RESEARCH QUESTIONS IDENTIFIED BY INVESTIGATORS

During the first meeting of the Care Consortium, participants were asked to identify gaps in knowledge regarding access to and delivery of effective, efficient, and equitable HIV/AIDS health services. The list that follows contains the questions and proposed research strategies produced in the brainstorming session. Subsequently, investigators prioritized the key areas in need of address from which the body of this research agenda was developed.

- What factors influence physician decision-making regarding adherence?
- How do patient/provider characteristics interact in clinical encounters?
- How can we discover and understand variation (e.g., geographic, organization type, provider/physician type) in practice patterns?
- How can we test and improve the specificity and sensitivity of measures used in health services research?
- What is case management?
- What is a case manager?
- What specific components constitute case management?
- How can increments of case management be understood for measurement purposes?
- What is the cost of case management and care coordination?
- What is the effect on health outcomes of having multiple case managers?
- How can case management be understood in the context of other/all ancillary services?
- Does case management affect risk behavior?
- What is the impact of migratory patterns on access to and continuity of care, and what are the subsequent health outcomes, both in terms of prevention and treatment?
- How does individual coping behavior facilitate or impede access?
- How can adherence be measured accurately for mobile groups?
- How can we develop standardized ways to measure cost and benefits of policy interventions?
- What links exist between research results and policy formation?
- How can measures of translation be developed?
- How can a controlled clinical trial of case management be undertaken?
- What are the factors influencing treatment durability and sustainability?
- How do these factors influence health outcomes?
- How can qualitative research be used to understand participant withdrawal from research?
- Which intervention models can increase access to care?
- How can information systems (and other systems interventions) affect care delivery and quality?
- What social and structural factors need to be in place to incentivize adherence?
- Are there models for helping clinicians facilitate patient adherence (for example, computerized patient assessment tools)?
- How does a newly infected person encounter the health services setting?
- How do patients' belief systems affect willingness to see and receive care?
- What role does health care socialization play relative to health outcomes?
- What are the incentives for non-adherence and how can they be modified?
- How can instruments be developed to assess institutional relationship to the patient?
- Why aren't people with AIDS accessing HAART?
- What are the causes of death among people with HIV?
- What is the impact of mixed public insurance eligibility on family health?
- What are the effects of back-to-work programs for quality of life and self-worth?
- What are long-term outcomes for patients with HIV in California?

- Is one comprehensive model of care better than other models or multiple delivery sites?
- What are the costs and benefits of comparative models of care delivery?
- What are the priority needs of emerging populations?
- How can providers be effectively trained to do prevention education in health care settings?
- What is the effect of state-funded resistance-testing programs?
- How are primary care and other providers linking clients to services?
- What are the major social barriers to receiving care?
- What is the impact of funding streams on care?
- How do we make health care data more accessible and useful?
- How can we collaborate for use of multiple data sources?

APPENDIX B: ROSTER OF THE CALIFORNIA CONSORTIUM ON HIV/AIDS HEALTH SERVICES RESEARCH

Donald I. Abrams, MD University of California, San Francisco Community Consortium	Ricardo Alvarez, MD Clinica Esperanza Mission Neighborhood Health Center
David R. Bangsberg, MD, MPH University of California, San Francisco	Grant Colfax, MD San Francisco Department of Public Health
Myrna Cozen, MPH University of California, San Francisco AIDS Policy Research Center	William E. Cunningham, MD, MPH University of California, Los Angeles Department of Health Services
Fred Dillon San Francisco AIDS Foundation	Lorraine Garcia Jaecks University of California, Los Angeles
Scot Hammond University of California, San Francisco Community Consortium	Susan Jacobson, MD East Bay AIDS Research Institute
Thomas Mitchell, MPH University of California, San Francisco Community Consortium	Michael Montgomery Office of AIDS California Department of Health Services
Stephen F. Morin, PhD University of California, San Francisco AIDS Policy Research Center	Kaarina Ornelas San Francisco AIDS Foundation
Susan Sabatier Office of AIDS California Department of Health Services	Herminia Palacio, MD, MPH San Francisco Department of Public Health
Gwen van Servellen, RN, PhD University of California, Los Angeles School of Nursing	Starley Shade, MPH University of California, San Francisco Community Consortium
Mitchell Wong, MD University of California, Los Angeles Division of General Internal Medicine and Health Services Research	

**APPENDIX C: RESEARCH PRIORITY-SETTING WORKGROUP
MEMBERSHIP**

Research Area	Team Members
Case Management	David Bangsberg, Grant Colfax, Myrna Cozen, Billy Cunningham, Kaarina Ornelas
Payer Source and Continuity of Care	Myrna Cozen, Fred Dillon, Herminia Palacio
Patients and Providers Communicating Adherence	Ricardo Alvarez, Susan Jacobson, Lorraine Garcia Jaecks
Long-term Health Outcomes	Tom Mitchell, Scot Hammond, Donald Abrams, Starley Shade
Provider-level Influences on Patient Access to Care	David Bangsberg, Mitchell Wong, Gwen van Servellen, Scot Hammond

APPENDIX D: PRIORITY RECOMMENDATIONS FOR CARE AND TREATMENT RESEARCH AND EVALUATION

Generated at the Conference on HIV/AIDS Care and Treatment Research in California, September 1999, San Diego, California

- ❑ **Develop** ways to integrate multiple factors in researching patterns of access, utilization, cost, and quality. Social context and sociodemographic factors should be considered alone and in interaction.
- ❑ **Explore** patient characteristics such as ethnicity, socioeconomic status, sexual orientation, and gender.
- ❑ **Include** in research structural factors such as stigma, historical bias, the everyday context of peoples' lives, the structure of the health care system, and cost reimbursement systems.
- ❑ **Seek** input from the community at the conception of a research or evaluation project.
- ❑ **Match** the research question to the appropriate level of service: patient, provider, organization, system, community, or population.
- ❑ **Undertake** sentinel studies of at-risk populations. These studies will provide a knowledge base for understanding HIV infection and care-seeking behavior across sub-populations and will provide information on the actual need and demand for care among those with and without access to care.
- ❑ **Engage** in measurement beyond primary care.
- ❑ **Include** qualitative methods to complement quantitative results, especially for program planning purposes.
- ❑ **Build** research capacity in research settings and within service delivery programs.
- ❑ **Develop** core data elements and best practices to encourage valid, reliable research.
- ❑ **Increase** capacity for sustainable evaluation in service delivery settings.
- ❑ **Treat** dissemination of results as an integral part of doing research.
- ❑ **Consider** how the results of research will be disseminated from the inception of the research design.
- ❑ **Prepare** and distribute results for use by all stakeholders including consumers, providers, policy makers, and funders.



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